

**IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

NIPPON SHINYAKU CO., LTD., Plaintiff,)	
v.)	
SAREPTA THERAPEUTICS, INC.,)	C.A. No. 21-1015 (JLH)
Defendant.)	
)	
SAREPTA THERAPEUTICS, INC.,)	
Defendant and Counter-Plaintiff)	
v.)	
NIPPON SHINYAKU CO., LTD. and)	
NS PHARMA, INC., Plaintiff and Counter-)	
Defendants.)	

**NIPPON SHINYAKU CO. AND NS PHARMA, INC.'S
LETTER REGARDING REQUEST FOR LEAVE TO FILE
MOTION FOR SUMMARY JUDGMENT**

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*Attorneys for Plaintiff/Counterclaim Defendant
Nippon Shinyaku Co., Ltd. and Counterclaim
Defendant NS Pharma, Inc.*

Dated: September 26, 2024

Dear Judge Hall:

Pursuant to the Court's July 2, 2024 Order (D.I. 597), Plaintiff/Counter-Defendant Nippon Shinyaku Co., Ltd. and Counter-Defendant NS Pharma, Inc. (collectively, "NS") move for leave to file a motion for summary judgment regarding invalidity of the sole remaining asserted claim 1 of the sole remaining patent asserted by counter-plaintiffs Sarepta Therapeutics, Inc. and the University of Western Australia (collectively, "Sarepta")—U.S. Patent No. 9,994,851 (the "'851 Patent"). Supplemental expert discovery has confirmed that the '851 Patent is invalid for lack of written description and enablement, no material disputes of fact remain regarding these invalidity legal issues, and, thus, the Court should address this issue before trial.

This Court clarified its claim construction that claim 1 of the '851 Patent "requires 100% complementarity to consecutive bases of a target region of exon 53 throughout the entire length of the antisense oligonucleotide." D.I. 573. Based on this, each side's experts served supplemental expert reports and have subsequently been deposed. The record developed during this supplemental expert discovery period leaves no material factual dispute regarding the invalidity of the '851 Patent. Thus, this legal issue is ripe for the Court's consideration. Granting summary judgment in favor of NS regarding the invalidity of the '851 Patent will greatly simplify issues for trial and conserve Court and party resources.

The Court should grant summary judgment of invalidity in favor of NS based on undisputed facts and pure legal issues as outlined below:

First, claim 1 of the '851 Patent is invalid for lack of written description. As demonstrated in the proposed Statement of Undisputed Facts filed contemporaneously herewith, Sarepta's expert Dr. Dowdy cannot dispute that the scope of claim 1 of the '851 Patent is very large—encompassing thousands of unique configurations of antisense oligonucleotides. Yet, the specification of the '851 Patent fails to demonstrate that a single candidate meeting the claims' structural limitations causes the required function of exon skipping, let alone a representative number of species. Nor does the specification disclose structural features or structural correlation to the claimed exon 53-skipping function, so Sarepta cannot satisfy the written description requirement.

Second, claim 1 of the '851 Patent also is invalid because it is not enabled. The claim is broadly directed to a range of exon 53 skipping, from "very faint" to complete, yet there is no dispute that at most the specification only enables a POSA to make an AO with "very faint" exon skipping and provides no guidance on how the POSA could modify an AO to increase its skipping efficacy. Allowing a jury to determine whether claim 1 of the '851 Patent is enabled directly contradicts binding Federal Circuit and Supreme Court precedent where claims with far more specification support have been held to be non-enabled. No factual disputes regarding this enablement issue remain for the jury, and the Court should thus decide this issue as a matter of law now to streamline issues for trial.

* * *

NS seeks to conserve judicial resources, streamline the trial in this matter, and have the Court resolve the purely legal invalidity issues raised in its motion for summary judgment (Ex. A hereto, with accompanying memorandum of law in support attached as Ex. A-1, and statement of undisputed facts attached as Exhibit A-2). NS therefore respectfully requests the Court grant it

leave to file the attached motion for summary judgment and resolve the motion prior to the scheduled December 2024 trial.

Dated: September 26, 2024

Respectfully submitted,

MORGAN, LEWIS & BOCKIUS LLP

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